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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,537	03/29/2005	Jean Paul Remon	50304/070001	4574

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CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

EXAMINER
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WESTERBERG, NISSA M

ART UNIT	PAPER NUMBER
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1618

NOTIFICATION DATE	DELIVERY MODE
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02/28/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/529,537	<b>Applicant(s)</b> REMON ET AL.	
	<b>Examiner</b> Nissa M. Westerberg	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-37 is/are pending in the application.
- 4a) Of the above claim(s) 32-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-31 is/are rejected.
- 7) ☒ Claim(s) 29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/29/05; 11/2/05</u>  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of group I and the presence of a plastifying agent in the reply filed on January 18, 2008 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

### ***Status of Claims***

Claims 19 – 37 are pending. Claims 32 – 37 are withdrawn as not being drawn to the elected invention. Claims 19 – 31 are currently under examination.

### ***Comments and Notes***

On page 6, a section is present entitled "Detailed Description of Drawings", which appears prior to the "Detailed Description of the Invention" on the following page. The section before the "Detailed Description of the Invention" is customarily the "Brief Description of the Drawings" and since the figures are explained in further detail later in the specification, it is kindly suggested that Applicant re-title the section on p 6 to a brief, rather than detailed, description of the drawings.

### ***Claim Objections***

2. Claim 29 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 27. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Claim Rejections - 35 USC § 112 2<sup>nd</sup> Paragraph***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what chemical species are included in the list from which the plasticizer component can be selected from. For example, starting in line 7 of the claim, it is not clear whether fatty acids and esters thereof with polyethylene glycol is one item and propylene glycol is another plasticizer that may be selected or if an ester of a fatty acid with propylene glycol is the second item in that section which may be selected. A similar confusion exists beginning in line 6 with if esters formed between glycerol and acetic acid is one item and sugars is a separate item in the list of esters formed between glycerol and sugars are included. If Applicant intended that fatty acids

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ester with either polyethylene glycol or propylene glycol be encompassed, it is suggested that Applicant use semi-colons to clearly delineate each separate item of the list and then use commas within each item to delineate possible combinations within that item.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 19, 23, 24, 27, 29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Bar-Shalom (WO 95/22962, whole document, cited on PTO-1449).

In regards to claims 19, 23, 24, 27, 29 and 31, example 2 (p 19, ln 4 – 17) of Bar-Shalom discloses a solid composition comprising a coating (outer layer) and a matrix (inner core). The outer layer comprises the hydrophobic cellulose polymer ethylcellulose (p 15, ln 20 – 22 of the instant application) and the plasticizer cetostearyl alcohol (p 7, ln 30; p 8, ln 2 – 3). The inner core comprises the hydrophilic cellulose polymer hydroxymethylcellulose and the amphiphilic material polyethylene glycol 2000 stearate. The stearate portion is hydrophobic while the polyethylene glycol 2000 is hydrophilic. The ratio of the cellulose component to the amphiphilic component is 0.3:1. The inner core further comprises tartrazine which can be a cosmetic agent, as evidenced by its

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use as coloring agent generally used in makeup cosmetic compositions (US Patent 6,024,950; col 4, ln 6 – 8; ln 21). The amount of tartrazine present in the total composition is 1% by weight. Cosmetic agents are included in the definition of biologically active agent given by Applicant on p 10, ln 12 – 17 of the instant specification.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 19, 20 and 23 – 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-Shalom (WO '962).

As discussed above, Bar-Shalom discloses solid compositions comprising an outer layer with a plasticizer and a polymeric component and an inner core comprising a biologically active ingredient, at least one hydrophilic cellulose polymer and an amphiphilic material. In example 2, the ratio of the hydrophilic cellulose polymer to the amphiphilic material is 0.3:1.

Bar-Shalom states that the matrix comprises a crystalline polyethylene glycol polymer and at least one non-ionic emulsifier (an amphiphilic compound). In that matrix, the non-ionic emulsifier is present in an amount of 2 – 50% by weight. The amount of the compounds present would be adapted depending on the specific compounds used and the desired release of the active ingredient (p 6, ln 19 – 24). The composition may also be made from the cellulose derivatives that are described as being suitable for the coating (p 6, ln 12 – 19). Examples of celluloses that may be used include hydroxymethylcellulose (the cellulose compound used in example 2) as well as hydroxypropylmethyl cellulose (p 7, ln 18 – 19).

While ethylcellulose is a preferred component for the outer layer (p 7, ln 3 – 4), other hydrophobic cellulose polymers of the cellulose ether class may be used in the coating (p 6, ln 35 – p 7, ln 1). A wide variety of compounds may be used as plasticizers (p 7, ln 28 – p 9, ln 4). They include fatty acids esterified with polyethylene glycol (p 7, ln 33 – 34), fatty alcohols (p 8, ln 2 – 4) and the polyols polyvinyl alcohols (p 8, ln 13).

A wide variety of active ingredients can be included in the compositions (p 11, ln 12 - p 12, ln 32). Exemplified classes of active agents include drugs, vitamins, disinfectants, polypeptides, antimicrobial agents and anti-fungals. The amount of active substance can be as high 70%, but will typically be present in amounts up to 50% (p 13, ln 4 – 7). Much smaller amounts of active ingredient may also be present, depending on the nature and strength of the active substance (p 13, ln 9 – 12).

Based on about 2 – 50% of the inner core being the amphiphilic component and up to 70% being the active substance, the amount of polymer present in the core could vary widely. With 2% amphiphilic component and 70% active substance, only 32% (or less, if other ingredients are also present) of the inner core could be the hydrophilic cellulose polymer such as hydroxymethylcellulose or hydroxypropylmethylcellulose.

The various ingredients as well as the amounts of those ingredients claimed in the instant application are disclosed by the prior art. It would be obvious to one of ordinary skill in the art to replace one component with a functional equivalent with a reasonable expectation of success. Therefore, the disclosure of the prior art renders the claims of the instant application obvious to one of ordinary skill in the art at the time of the instant invention.

11. Claims 19, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-Shalom as applied to claims 19, 20 and 23 – 31 above, and further in view of Santos et al. (US Patent 5,503,843).

Bar-Shalom discloses solid compositions comprising an outer later with a plasticizer and a polymeric component and an inner core comprising a biologically active ingredient, at least one hydrophilic cellulose polymer and an amphiphilic material. While Bar-Shalom et al. discloses a long list of plasticizers (p 7, ln 27 – p 9, ln 4), plasticizers with a portion derived from a glyceride and a portion derived from a polyethylene glycol ester are not disclosed.

Santos et al. discloses that many types of compounds can be used as plasticizer-type enhancers (col 8, ln 57 – col 9, ln 39). Some of the plasticizers exemplified in Bar-Shalom et al. such as stearyl and oleyl alcohol (p 8, ln ln 3 – 4) are also included in the list in Santos et al. The list of these plasticizer-type compounds in Santos et al. also includes polyethylene glycol-8 caprylic capric glycerides (LABRASOL®) and caprylic/capric triglyceride polyethyleneglycol-4 esters (LABRAFAC® Hydro WL 1219). Both of these plasticizers contain a glyceride portion and portion derived from a polyethylene glycol ester.

While Bar-Shalom discloses a long list of plasticizers, it is not a complete list of all compounds that can act as plasticizers. Santos et al. provides an overlapping list of compounds that can act as plasticizers. Since these lists of compounds or mixtures are functional equivalents, one of ordinary skill in the art at the time of the instant invention

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would have a reasonable expectation of success in replacing one plasticizer component in the outer layer with another plasticizer.

### ***Conclusion***

Claims 19 – 31 are rejected. Claim 29 is objected to. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NMW

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618